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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,232	01/15/2002	Willam John Martin		7880

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,232	MARTIN, WILLAM JOHN	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I in the reply filed on July 23, 2004 is acknowledged.

Claims 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 23, 2004.

Claims 1-8 are under consideration.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 8 is objected to because of the following informalities: the claim is drawn to a method of testing auto-fluorescence in nails, but the end of the claim states that the method is used to illuminate hairs. It is presumed that reference to hair is a typo. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

An asserted credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the disclosed invention is currently available for such use.

In the instant case, the claims are drawn to various methods of measuring fluorescence in hair and nails as relating to a stealth virus infection. These methods lack credible utility for several reasons.

The first issue is that there is no clear definition provided in the disclosure of what a stealth virus is. For example, on page 5, the disclosure states that a stealth virus infection was initially associated with psychiatric illness, chronic fatigue syndrome, and cancer. Further, on page 17, the disclosure states that due to stealth viruses having the capability of adopting and mutating genes from other viral, bacterial and cellular origins, the viruses are "easily misidentified as various types of conventional viral and bacterial pathogens". The disclosure also states that stealth viruses are commonly found in patients affected by Lyme disease, mycoplasma and herpesvirus-6 (HHV-6) infections. However, there is no guidance provided for how a clinician would distinguish stealth virus infected patients from patients affected by psychiatric illness, chronic fatigue syndrome, cancer, Lyme disease, mycoplasma and/or herpesvirus-6 (HHV-6) infections. It is not clear how these stealth virus infected patients were/are identified. It is also not clear whether the virus induces any detrimental effect on its own since patients identified as having stealth virus infection were already affected by and being

treated for other conditions. Since identification of distinguishing characteristics of a stealth virus infection is not provided, stealth virus infection cannot be determined, especially since the viruses are so easily misidentified as other viral or bacterial pathogens.

On page 15, stealth viruses are defined as infectious agents that induce a characteristic vacuolating cytopathic effect (CPE) in culture cells. However, this phenomenon does not aid in clearly identifying characteristics of the virus to one of ordinary skill in the art. To illustrate this point, the teachings of Sahagun-Ruiz et al. (Virus Genes. 2004; 28 (1): 71-83) is cited. Sahagun-Ruiz et al. describe five open reading frames (ORFs) that were sequenced from a prototype stealth virus. Sahagun-Ruiz et al. describe this virus as a "heterogeneous group of atypically structured putative viruses that have been isolated from patients..." (emphasis added). Sahagun-Ruiz et al. further state that "[t]he biological significance of this entity is not yet clear, and it has not been independently replicated in tissue culture. "Stealth virus" sequences submitted to Genbank include sequences also reported in African Green Monkey Simian Cytomegalovirus, bacterial, fungal and human genomes." See the first full paragraph of the second column on page 72 of Sahagun-Ruiz et al. From the discussion provided by Sahagun-Ruiz et al., it is clearly evident that stealth viruses have no distinguishing characteristics identifiable by those skilled in the art. In addition, since Sahagun-Ruiz et al. refer stealth viruses as "putative", it is apparent that there is doubt in the art as to whether stealth viruses even exist.

The working example on page 19 of the instant specification describes analyzing hair from a stealth virus infected patient. Hair fluorescence was determined from analysis of various metals present in the hair. For some metals, the interpretation provided for the data indicates that some metal concentrations were high. However, it is not apparent how the presence of various

metal concentrations fluorescing in hair correlates to a stealth virus infection, other virus infection or natural fluorescence in human. For example, Fellner et al. (International Journal of Dermatology. 1979; 18 (9): 722-30) teach that humans have natural fluorescing materials in hair, see the entire reference. In addition, the teachings of Bryceson et al. (Journal f Infectious Diseases. 1975; 131 (1): 71-74) and Williams et al. (Archives of Pathology and Laboratory Medicine. 1983; 107 (1): 40-45) indicate that rabies virus infection and herpes simplex virus infection, respectively, also induce autofluorescence in hair, see the disclosures of each reference. Instant claim 1 is drawn to a method to test for the ability of a stealth virus infection to induce the production of fluorescent materials in hair. From the data provided in the specification, it is not clear that the virus produces fluorescent materials in hair since there is no indication for how the stealth virus infected patient in the working example was identified as being infected. There is no discussion, explanation or data provided for how a virus would be able to induce the production of various metals in hair. Therefore, since there is no nexus between stealth viruses and fluorescing substances in hair, it is not credible to practice the methods claimed to test for variations of production of auto-fluorescent material in hair.

The methods of claims 4-8 do not involve stealth virus. Claims 4 and 6-8 are drawn to a method of testing for the production of auto-fluorescent materials in the hair or nails of a human or animal subject. However, a utility for this method is not clear from any disclosure in the specification or recitation in the claims. It is not evident what the results of the testing described by the method are intended to demonstrate. Claim 5, dependent upon claim 4, states that the method is performed to monitor the effectiveness of therapy directed as suppressing the production of auto-fluorescent materials in hair. However, there is no known condition that

indicates that the presence of fluorescing material in hair is a detrimental symptom for the host that requires treatment. There is also no known treatment for remedying or reducing the quantity of auto-fluorescent materials in hair.

Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648